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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/008,385

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Carol W. Readhead

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EXAMINER

HAMA, JOANNE

ART UNIT

PAPER NUMBER

1632

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/008,385	<b>Applicant(s)</b> READHEAD ET AL.	
	<b>Examiner</b> JOANNE HAMA	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 135,137,138,140-143 and 145-160 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 135,137,138,140-143 and 145-160 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant filed a response to the Non-Final Action of June 17, 2008 on December 18, 2008. Claims 1-134, 136, 139, 144 are cancelled.

Claims 135, 137, 138, 140-143, 145-160 are under consideration.

### **Maintained Rejections**

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 135, 137, 138, 140, 142, 143, 145-160 remain rejected under 35 U.S.C. 102(e) as being anticipated by Brinster et al., US Patent 5,858,354, patented January 12, 1999, previously cited, as evidenced by Cotten et al., 1995, Virology, 213-494-502, for reasons of record, June 17, 2008

Applicant's arguments filed December 18, 2008 have been fully considered but they are not persuasive.

Applicant indicates that Brinster et al. do not describe introduction of genetic material into male germ cells because Brinster et al. only describes modification of patent mouse stem cells. The only meaningful disclosure in Brinster et al. is concerned

Art Unit: 1632

with modification of mouse stem cells and the properties and makeup of pluripotent cells are different from germ cells, e.g., because of different chromosome numbers and active genes; and as such stem cells and germ cells can be expected to behave differently in response to the introduction of new material (Applicant's response, page 8). In response, this is not persuasive. With regard to Applicant indicating that there is a difference in chromosome number of stem cells and germ cells, claim 135 not exclusively drawn to introducing a polynucleotide to monoploid cells. Claim 135 includes diploid cells such as spermatogonial stem cells. As such, Brinster et al., who teach introduction of a polynucleotide to primitive cells, such as spermatogonial stem cells (Brinster et al. col. 5-7, especially col. 5, line 66), is readable on the claims.

Contrary to the Examiner's position, what Brinster et al. envisioned is clearly not disclosed beyond the disclosure of the work with embryonic stem cells. Based on Brinster et al., the transfection of "primitive" germ cells is pure speculation and that reference does not enable such transfection. Hence, a germ cell is not a stem cell and as such, Brinster does not describe the male germ cells of the invention. Just because a stem cell has been modified, this does not teach the process of modifying a cell that can differentiate from that stem cell. Brinster et al.'s material is clearly not relevant beyond the modification of stem cells and as such, Brinster et al.'s material cannot anticipate the present claims (Applicant's response, page 8). In response, this is not persuasive. Brinster et al.'s transfection of primitive germ cells is not speculation because Brinster et al. teaches that donor stem cells can be transfected in tissue culture before they are transplanted (Brinster et al., col. 12, 2nd parag.). With regard to

Art Unit: 1632

Applicant indicating that just because a stem cell has been modified, this does not teach the process of modifying a cell that can differentiate from that stem cell, the Examiner was not extrapolating Brinster et al.'s teaching. Claim 135 is drawn to introducing a polynucleotide to a male germ cell. One such male germ cell is a spermatogonial stem cell. Brinster et al. teach introduction of a polynucleotide to a spermatogonial stem cell. As such, Brinster et al. anticipate the claimed invention.

Thus, the claims remain rejected.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 135, 140, 141 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Brinster et al., US Patent 5,858,354, in view of Naldini et al., 1996, Science, 272: 263-267, see IDS filed May 20, 2004, for reasons of record, June 17, 2008.

Applicant's arguments filed December 18, 2008 have been fully considered but they are not persuasive.

Applicant indicates that as presented above, taken together with earlier analysis of Brinster et al., Brinster et al. clearly do not anticipate or teach the claimed method as the Applicant has shown that modification of a stem cell does not teach a process of

Art Unit: 1632

modifying a cell that can differentiate from that stem cell. Given the lack of relevance of Brinster et al. for at least the reasons discussed above, the material disclosed in Naldini et al. fails to provide missing features not found in Brinster et al., which would lead one of skill in the art to the present claims (Applicant's response, page 9). In response, this is not persuasive. As discussed above, Brinster et al. teach introduction of a polynucleotide to a spermatogonial stem cell, and as such, Brinster et al. anticipate the claimed invention. With regard to the claims being drawn to lentiviral vectors (claims 140, 141), Naldini et al. teach that lentiviral vectors can be used to deliver a transgene of interest. As such, at the time of filing, an artisan would have used a lentiviral vector to deliver a transgene of interest to a spermatogonial stem cell.

Thus, the claims remain rejected.

### ***Conclusion***

No claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1632

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

Art Unit: 1632

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/Joanne Hama/  
Primary Examiner  
Art Unit 1632